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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,421	06/11/1999	JOHN FRANCIS GORDON	043601/0110	2286

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,421

Applicant(s)

GORDON, JOHN FRANCIS

Examiner

P. Kathryn Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-155 is/are pending in the application.
- 4a) Of the above claim(s) 45-88, 100-104 and 132-155 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-99 and 105-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1743

DETAILED ACTION

1. Any rejection and/or objection not repeated herein has been withdrawn.

Response to Amendment

2. The amendment to the claims filed on April 23, 2003 does not comply with the requirements of 37 CFR 1.121(c) because claim 131 which previously depended on claim 123, now depends on claim 126. However, Applicant has not provided the required changes to the claims in the form of brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. Amendments to the claims filed after March 1, 2001 must comply with 37 CFR 1.121(c) which states:

(c) Claims.

(1) Amendment by rewriting, directions to cancel or add: Amendments to a claim must be made by rewriting such claim with all changes (e.g., additions, deletions, modifications) included. The rewriting of a claim (with the same number) will be construed as directing the cancellation of the previous version of that claim. A claim may also be canceled by an instruction.

(i) A rewritten or newly added claim must be in clean form, that is, without markings to indicate the changes that have been made. A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added (e.g., "amended," "twice amended," or "new").

(ii) If a claim is amended by rewriting such claim with the same number, the amendment must be accompanied by another version of the rewritten claim, on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of that claim. A parenthetical expression should follow the claim number indicating the status of the claim, e.g., "amended," "twice amended," etc. The parenthetical expression "amended," "twice amended," etc. should be the same for both the clean version of the claim under paragraph (c)(1)(i) of this section and the marked up version under this paragraph. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added claim or a canceled claim as it is sufficient to state that a particular claim has been added, or canceled.

(2) A claim canceled by amendment (deleted in its entirety) may be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1743

4. Claims 89-99, 105-131 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 89, 105 and 123 disclose the plate structure is provided encoded information associated with at least one of the upper and lower surfaces, the encoded information including address information for least one of the reaction sites. However, this limitation is not believed to be adequately supported within the instant specification. The specification describes the use of a *second embodiment* which depicts the multi-well assay plate in the form of a *disk 32* designed for use with a rotating scanning device having a CD player type format. This disk 32 is shown in Fig. 3. Additionally, one of the surfaces of the upper or lower plates 34, 36 may be provided with digitally encoded address information 39 which can be read by the scanned light beam. The specification does not support the use of the assay plate structure being provided with encoded information associated with at least one of the upper and lower surfaces, the encoded information including address information for least one of the reaction sites, with the embodiments which are *not* in the form of a disk, see page 12, line 21- page 13, line 25.

Moreover, the specification does not support the recitation of the “encoded information containing address information for at least one of the reaction sites”. The specification teaches that the address information can be used to provide accurate location information on the part of the disk which is being scanned by the light beam (page 13, 2nd paragraph). However, this does not support the encoded information containing address information for at least one of the reaction sites. Applicant is required to point out where support for the recitation of the encoded

Art Unit: 1743

information containing *address information for at least one of the reaction sites* can be found within the instant specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 89-93, 96, 98-99, 105-120, 123-129, 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Merkh *et al* (USP 5,281,540).

Croteau *et al* teach a multi-well assay disc plate 10 comprising; a lid, a second lower surface having a plurality of wells 12 disposed therein, the lid and second surface defining a chamber having an opening 24 which allows fluids to be introduced and withdrawn from the chamber. The plate is made from a hydrophobic material. Moreover, each well is adapted to hold an aliquot of liquid and is sized and shaped and formed of a suitable material to hold the aliquot with the well by surface tension. Additionally, the surface of the wells can be treated with

Art Unit: 1743

a hydrophilic material to enhance the retention of the liquid in the wells (column 2, lines 43-45, column 4, line 52- column 6, line 60, Figs. 2A-4B).

Croteau *et al* do not teach a disc structure which is divided into removable sectors. The disc structure including digitally encoded address information including address information for at least one of the reaction sites. Merkh *et al* do teach a disc structure 18 which is divided into sector inserts 80 comprising wells 84. The system of Merkh *et al* includes a liquid injecting device 31 which penetrates the self-sealing cover 90 of each sector at port 92 (column 10, lines 1-7). Merkh *et al* teach the sector insert having digitally encoded address information 94 for use with a device having an optical inspection means 316. The locations of each test cartridge 80 is provided by the bar code 94 via optical code reader 316 to the microprocessor 315 such that the microprocessor can control the interfacing of the various mechanical elements (probe 30) of the analyzer with the cartridge. The test cartridges comprise at least one reaction site 84, therefore knowledge of the location (e.g. address) of the test cartridge provides the address information for at least one of the reaction sites. At the end of the test cycle when the optical reader 32 reads the assay results from the test sites 84 on each cartridge 80, the microprocessor 315 retrieves the lot code for each cartridge 80 and compares it with the lot codes previously stored in the table 312. When a match is found, the microprocessor 315 uses the corresponding starting storage location in the table 312 to retrieve the actual calibration data 300 from the storage area 314. The microprocessor 315 then uses the calibration data 300 to normalize the assay result for each test site 84, using a regression analysis technique in a manner well known to those skilled in the art (column 30, line 51- column 32, line 54, Figs.1-2, 4-5, 14)..

Moreover, Merkh *et al* teach sectors inserts and a disc which include lock 100, 102, 104 and

Art Unit: 1743

key 93 portions to allow the sectors to be snap-fitted in the correct orientation and the disc comprising plurality of dividing walls 122.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of Croteau *et al* the digitally encoded address information means, as taught by Merkh *et al*, in order allow the operator to easily access patient information corresponding to the particular assay sector (column 10, line 60- column 11, line 21).

Croteau *et al* discloses the claimed invention except for the spacing between the upper and lower plates less than 1.0 or 0.5 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to made the spacing between the upper and lower plates less than 1.0 or 0.5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. Claims 97, 116 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Merkh *et al* (USP 5,281,540) as applied to claim 96 above, and further in view of Takase *et al* (EP 417 305 A1).

Croteau *et al* as discussed previously, do not teach wherein either of the upper or lower plates includes a reflecting surface. Takase *et al* teach a liquid sample analyzer. The analyzer comprising a disc 101 with wells 104 and liquid sample supply means 9 for supplying liquid sample to the wells. Additionally, the analyzer system comprises a measuring means for measuring the reaction product produced. The disc has information formats 101, i.e. digitally encoded information, needed for analysis. The formats can be processed via a reflection method

Art Unit: 1743

in which a reflecting film 101b can be formed on the upper or lower plates. A reading head 19 is arranged above and/or below the formats to provide the predetermined information (page 11-12, Fig. 8b).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included the within the disc of Croreau *et al*, with the reflective surface in order to provide a reliable and permanent means of storing information pertaining to the reaction disc.

9. Claims 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Merkh *et al* (USP 5,281,540) as applied to claim 105 above, and further in view of Ford (USP 4,722,598).

Croteau *et al* as discussed above, do not teach an assay plate including one or more lenses molded into the structure to improve the optical inspection of the surface locations. Ford does disclose a base and cover plate. The base plate includes shallow wells 4 for holding a biological sample. The base plate includes thin transparent bottom lens 7 that is integrally formed and which define the bottom of each sample well (column 3, lines 1-68, Figs. 1-8). Such use of a bottom lens avoids any optical distortion which might occur during microscopic observation of the sample contained in the various sample wells (column 3, lines 60-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included the within the assay plate of Croreau *et al*, the integrally molded lens, in order to avoid any optical distortion which might occur during microscopic observation of the sample contained in the various sample wells.

Response to Arguments

Art Unit: 1743

10. Applicant's arguments filed April 23, 2002 have been fully considered but they are not persuasive. In response to the previous rejection of the instant claims, Applicant's arguments do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

11. No claims allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to

Art Unit: 1743

3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex
P. Kathryn Bex
Patent Examiner
AU 1743
May 19, 2003

Jill Warden
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